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Caldolor® Pediatric Fever Study Published Supporting Its Efficacy, Safety And Pharmacokinetics

Caldolor reduces fever in pediatric patients with a favorable safety profile

NASHVILLE, Tenn., Feb. 7, 2017 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)** today announced the publication of a multicenter clinical study demonstrating that Caldolor® (*ibuprofen)* Injection delivered significant fever reduction in hospitalized children. This study, which adds to the growing body of literature supporting Caldolor, evaluated the efficacy and safety of intravenous ibuprofen in pediatric patients, six months and older, with fever. This pivotal data supported the FDA approval of Caldolor for use in this pediatric patient population.

Fever is one of the common symptoms seen by health care providers and one of the leading reasons children and infants present for medical evaluation. Oral forms are commonly used in hospitals to treat pediatric patients who develop fevers. However, patients presenting to the emergency department, undergoing surgery, or those admitted to the hospital are frequently unable to take their medications orally.

This randomized, open-label study evaluated the efficacy, safety, and pharmacokinetics of intravenous ibuprofen in hospitalized pediatric patients. It was conducted across fourteen sites within the United States, enrolling one hundred and three hospitalized pediatric patients sixteen years of age or younger with a fever greater than or equal to 101.0° F (38.3° C).

Results from the study demonstrated that a single 10 mg/kg dose of intravenous ibuprofen provided a significant reduction of temperature for pediatric patients and provides an effective option for reducing fever in the pediatric patient population. The new publication is currently available as an open access article in the British BMC Pediatrics Journal.

About Caldolor® (ibuprofen) Injection

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other

NSAIDs, patients with a history of asthma or other allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of high-quality products that improve the quality of care for patients. The Company has a diverse product portfolio with a focus in the areas of hospital acute care and gastroenterology.

Cumberland's marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia, Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease, and Ethyol® (*amifostine*) for Injection, for the prevention of treatment-related adverse reactions in oncology patients. Cumberland is also dedicated to developing innovative products that address unmet medical needs.

The Company's product candidates in clinical development include: Hepatoren® (*ifetroban*) Injection for the treatment of hepatorenal syndrome, Boxaban® (*ifetroban*) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, Vasculan™ *(ifetroban*) Oral Capsule for the treatment of systemic sclerosis and Portaban™ *(ifetroban*) Oral Capsule for the treatment of portal hypertension.

For more information on Cumberland Pharmaceuticals Inc., please visit www.cumberlandpharma.com.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/caldolor-pediatric-fever-study-published-supporting-its-efficacy-safety-and-pharmacokinetics-300403097.html

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